III. METHODOLOGY TO DETERMINE BIOMATERIAL STOCKPILE LIMITS ON THE BASIS OF DANGER CLASSIFICATION GROUPS

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Among measures to strengthen the 1972 Convention, verifiable limitations on biomaterials capable - with certain efforts - to form the basis of bacteriological (biological) weapons (BW)* will apparently play a central role.

Development of a balanced system of verification and limitations seems to be an extremely complex task: on the one hand, it is desirable that all pathogenic agents, potentially dangerous for use in combat or sabotage purposes, should be subject to verification; on the other hand, limitations on biomaterials containing these pathogenic agents should not slow down research or hamper production and commercial activities, while preventing the threat of BW sevelopment.

First steps taken by the American side to solve this task - a list of potentially dangerous agents, as well as proposals to divide the agents into three classification groups (E, S and N) and to set a quantitative limit for each group - can be welcomed and basically approved.

The proposals prepared by our American collegues are not devoid of shortcomings, which was clearly manifested during the discussions at the London and Moscow meetings. While

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*The author does not consider here microbial toxins

the list of pathogenic agents, agreed after two round of discussions, can today be considered correct enough, the same, unfortunately, can not be said about the quantitative limits. A single limitation level, particularly for pathogenic agents of group "S", is unacceptable, since this group includes the overwhelming majority of agents with an extremely wide range of biological characteristics; and what is more important, the unit of measurement of biomaterial stockpiles - ID_{50} - has not been determined practically for all viruses falling into this group. Such a "universal" limitation scale may entail excessively rigid regulations for the stockpiles of some not so dangerous agents, while permitting unjustifiably high and even threatening levels of really dangerous viruses.

The foregoing, in our opinion, convincingly shows that this is a complicated problem and impels us to search for ways to overcome it.

The following solution is proposed as a way out of the existing situation:

1. The American pattern, subject to the adjustment of quantitative limitations for a number of agents, is accepted on a temporary basis. The Soviet side will present relevant specific proposals during the next meeting.

2. Along with that, special extensive and rather long-term research is undertaken in order to determine the list of potential BW agents and stockpile limits on dangerous biomaterials.

Research should be based on a systematic approach to the problem, which will allow to identify priority areas and clearly set the sequence of solving particular issues during different stages.

Stage 1. Compilation of a list of potential BW agents as a working hypothesis.

At this stage all epidemiologically significant agents should be assessed from the point of view of their applicability for military and sabotage purposes judging by the whole range of criteria (epidemiologica, military and tactical, technical and economic).

This stage is of crucial importance, since it guarantees against "deviation" from the potential BW agents list of those microorganisms and viruses which belong there, while preventing the inclusion into the list of some "extraneous" agents. The last point is of critical importance, for an unjustifiable expansion of controlled items and limitations is undesirable not only because it hampers scientific and research activities but also from the point of view of preserving the efficiency of verification and limitation measures.

At this stage research should be carried out with the widest possible participation of scientists and specialists from different countries, and there is no doubt that the systematic analysis of scientific data in the fields of epidemiology, virusology and other medical, medico-social and biological sciences - which is indispensable for the realization of this stage - will give a powerful impetus to the world-wide and national health systems in strengthening their epidemic control activities.

Stage 2. Determination of ID_{50} (for human beings) of microorganisms and viruses included in the potential BW list on the basis of Stage I research.

This stage should use a wide range of scientific data, including investigation reports in connection with inner laboratory contaminations and inner hospital infections, results of volunteer tests, as well as materials of experimental research with animals and other biological test systems. The larger part of research at this stage, however, should consist of test system experiments in order to obtain base-line data to extrapolate ID_{50} to human beings.

It is advisable to organize the work on the basis of several laboratories and to carry it out by commissions composed of specialists from different countries, with participation of WHO experts.

Stage 3. Elaboration of the list of potential BW agents on the basis of data obtained during Stage 2. Determination of danger classification groups. Distribution of potential BW agents by classification groups.

A possibility that upon completion of this stage the number of danger classification groups will match the number of existing groups - E, S, N - can not be ruled out, yet it is much more probable that this number will increase.

Stage 4. Determination of differential stockpile limits on biomaterials containing potential BW agents for various danger categories and types of facilities (scientific and practical laboratories, pilot production installations, industrial enterprises etc.). Completion of the system of verifiable limitations.

This stage, which concludes and sums up the results of multi-disciplinary research, is to provide the United Nations with a reliable instrument to deter the BW threat.

Established quantitative limitations, as well as the list of potential BW agents should be periodically reviewed, for example, every 5 or 10 years. It is difficult to predict future developments, yet the list will probably show a tendency to shrink as a result of exclusion of agents which will become useless for military applications. However, inclusion of newly isolated agents is also possible. The evolution of the list, including the distribution of agents by danger classification groups, will, undoubtedly, be related to the development of medico-biological sciences, as well as to the state of international relations.

The proposed methodology for the determination of stockpile limits on potentially dangerous biomaterials is merely outlined, and painstaking consideration and discussions are needed to work out all its details and technicalities. If the American side shows interest in our concept and informs us to this effect, we shall be ready for a substantive dialogue at our next meeting.